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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,649	11/02/2007	Joo-Sung Yang	HANOL-10988	4858

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EXAMINER	
BABIC, CHRISTOPHER M	

ART UNIT	PAPER NUMBER
1637	

MAIL DATE	DELIVERY MODE
09/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/581,649	YANG ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER M. BABIC	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/15/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group II, claims 3-7, in the reply filed on June 15, 2009 is acknowledged.

Information Disclosure Statement

Applicant is advised that if an English translation of a cited foreign language reference is not provided, it will not be considered. Abstracts will be considered if a proper translation is provided.

Specification

The disclosure is objected to because of the following informalities:

The "Brief Description of Drawings" refers to only figure 7 and not figure 7A and 7B (see MPEP 608.01(f)).

Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim(s) 3-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jeney et al. (WO 03/076667 A1; 18 September 18, 2003), in view of NCBI (Accession No. M14119, 02-June-1994; OR Accession No. K02718, 18-March-1994; OR Accession No. AY262282, 28-April-2003; OR Accession No. J043553, 18-March-1994), and in further view of Lowe et al. (Nucleic Acids Research, Vol. 18, No. 7, page 1757-1761, 1990).

Jeney teaches the PCR amplification of human papillomavirus (HPV) regions (summary, pg. 7-9, for example). Specifically, the reference teaches the production and use of type-specific primers for the HPV L1 gene (pg. 14, SEQ ID NOs: 1-36, including HPV types 11, 16, 18, 31, for example).

The reference does not expressly teach the sequences recited in SEQ ID NOs: 1-7.

First, it is noted that the full genomes including the L1 gene sequence of HPV types 11, 16, 18, and 31 was known at the time of invention. NCBI provides a supportive disclosure that teaches the entire polynucleotide sequence of the L1 gene of HPV types 11, 16, 18, and 31 (see Accession No. M14119 for SEQ ID NOs: 1,2; Accession No. K02718 for SEQ ID NOs: 3,4; Accession No. AY262282 for SEQ ID NOs: 5,6; Accession No. J043553 for SEQ ID NOs: 7,8). Thus, the prior art taught sequences that comprised the full sequence recited in SEQ ID NOs: 1, 3, 5, and 7 as well as the full-complement to SEQ ID NOs: 2, 4, 6, and 8.

For example, see GenEmbl search for SEQ ID NO:1 below:

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RESULT 9
PPH11
LOCUS       PPH11                    7931 bp    DNA     circular VRL 02-JUN-1994
DEFINITION  Human papillomavirus type 11 (HPV-11) complete genome.
ACCESSION   M14119
VERSION     M14119.1  GI:333026
KEYWORDS    complete genome.
SOURCE      Human papillomavirus type 11
  ORGANISM  Human papillomavirus type 11
            Viruses; dsDNA viruses, no RNA stage; Papillomaviridae;
            Alphapapillomavirus.
REFERENCE   1  (bases 1 to 7931)
  AUTHORS   Dartmann,K., Schwarz,E., Gissmann,L. and zur Hausen,H.
  TITLE     The nucleotide sequence and genome organization of human papilloma
            virus type 11
  JOURNAL   Virology 151 (1), 124-130 (1986)
   PUBMED   3008427


  Query Match             100.0%;  Score 20;  DB 10;  Length 7931;
  Best Local Similarity   100.0%;  Pred. No. 23;
  Matches   20;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          1 TTAGGCGTTGGTGTTAGTGG 20
              ||||||||||||||||||||
Db       6098 TTAGGCGTTGGTGTTAGTGG 6117
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Lowe provides a supportive disclosure that teaches a method for designing primers and evaluating their performance wherein a computer program is used for rapid selection of oligonucleotide primers for polymerase chain reaction (see page 1757, col.

1, abstract). The references teaches that all primers designed for over 10 gene products were experimentally tested and the results showed that all the amplification products specified by the primers are of the predicted size and also hybridize with the appropriate cDNA or internal oligonucleotide probe (see page 1760, col. 2, paragraph 1).

It would have been *prima facie* obvious to a person of ordinary skill in the art at the time the invention, to combine the known HPV nucleic acid sequences as taught by the prior art with a step of generating and designing primers as taught by Lowe to amplify and increase the primer specificity and to detect the L1 gene of specific types of HPV because such gene sequences were known (as taught by Jeney and NCBI) to an at the time the invention was made, and it is obvious to generate primers from the known sequences as taught by Lowe. The ordinary artisan would have had a reasonable expectation of success that such primers or primer pairs generated using known sequences as taught by NCBI in view of Lowe to amplify L1 HPV DNA for detection because the claimed primers are functional equivalents of the sequences taught by Jeney and Lowe explicitly taught that all primers designed for over 10 gene products were experimentally tested and the results showed that all the amplification products specified by the primers are of the predicted size (see page 1760, col. 2, paragraph 1). The ordinary artisan would have been motivated to generate a number of said primers and primer pairs for detection of L1 HPV DNA to provide flexibility and optimize experimentation. Selection of specific oligonucleotides for specific T_m represents routine optimization with regard to sequence, length and composition of the

oligonucleotide. Such optimization parameters are explicitly recognized in Lowe (This clearly shows that every primer would have a reasonable expectation of success). As noted in *In re Aller*, 105 USPQ 233 at 235, more particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the primer selection performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 814-880-9945. The examiner can normally be reached on Monday-Friday 10:00AM to 6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christopher M. Babic/
Primary Examiner
Art Unit 1637
Technology Center 1600